Remarks

By this Amendment, claim 1 has been canceled, claim 2 has been amended, and new claims 3-4 have been added. Amended claim 2 includes additional limitations relating to the recited coupling means. New independent claim 4 is similar to amended claim 2, but without the recitations of use of the mesh.

Claim 1 has been provisionally rejected based on the judicially created doctrine of obviousness-type double patenting. Any such rejection is now moot in view of the cancellation of claim 1 by this Amendment.

Claim 2 has been provisionally rejected based on the judicially created doctrine of obviousness-type double patenting over claim 12 of co-pending U.S. Application Ser. No. 10/191,572. By Amendment dated December 13, 2005 (a copy of which is attached hereto), claim 12 has been canceled from U.S. Application Ser. No. 10/191,572, rendering the provisional rejection moot. Claim 2 has also been rejected based on obviousness-type double patenting over claim 20 of U.S. Patent No. 6,273,852. Claim 2 has been amended to recite first and second mesh coupling means having "recesses in the second ends" thereof, wherein the recesses are "dimensioned to receive therein and form a tight interference fit with the distal end of the needle." These additional recited features are not taught or suggested by the '852 patent, and thus applicants believe that claim 2, as amended, is patentably distinct from claim 20 of the '852 patent.

Claim 2 has further been rejected under 35 U.S.C. § 102(b) as being anticipated by the cited Staskin et al. article, Norris et al. article, O'Donnell article, and also under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,899,909.

With regard to the Staskin, Norris and O'Donnell articles, the Examiner has indicated that the "coupling means" recited in claim 2 reads on sutures that are secured to the mesh or graft in each of these articles. Although applicant does not agree with the Examiner's rejection, in the interests of expediting allowance and issuance of the present application, applicant has amended claim 2 to further recite that the

> first and second mesh coupling means are each fixedly secured at a first end thereof to the respective first and

second ends of the mesh, **and each have a recess therein at a second end**,

and to further recite that

the recesses in the second ends of the first and second coupling means are **dimensioned to receive therein and form a tight interference fit with the distal end of the needle to thereby enable the needle element to be removably coupled to the mesh**.

Neither Staskin, Norris or O'Donnell teach or suggest a coupling means having the features recited above, and thus fail to anticipate amended claim 2. New independent claim 4 includes similar limitations relating to the recited coupling means. As such, applicant submits that amended claim 2 and new claim 3 which depends therefrom, and new independent claim 4 are patentable over the cited articles.

With regard to the Examiner's rejection in view of the '909 patent, the Examiner has indicated that the "coupling means" recited in claim 2 reads on the shrink hose described therein. As indicated above, amended claim 2 and new claim 4 recite a coupling means or coupling element having a recess in one end capable of receiving and forming an interference fit with the distal end of the needle element. Applicant believes that this recited feature clearly distinguishes over the device disclosed in the '909 patent.

In view of the foregoing, applicant believes that pending claims 2-4 are in condition for allowance, which is respectfully requested.

Although no fee is believed to be due in connection with this Amendment, the Commissioner is hereby authorized to charge any such fee to deposit Account No. 10-0750/GYN-0090/MJS. This Authorization is being submitted in triplicate.

Respectfully submitted,

/Melissa J. Szanto/

Melissa J. Szanto
Attorney for the Applicants
Reg. No. 40,834

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-1365
DATED: December 13, 2005

Docket No. GYN-0124

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Kammerer et al.

Serial No. : 10/191,572 Art Unit: 3736

Filed : July 9, 2002 Examiner: John P. Lacyk

For: SURGICAL INSTRUMENT AND METHOD FOR TREATING FEMALE URINARY INCONTINENCE

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on

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Melissa J. Szanto
(Name of applicant, assignee, or Registered Representative)

/Melissa J. Szanto/
(Signature)

December 13, 2005
(Date of Signature)

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Response to Office Action Dated October 5, 2005

Dear Sir:

This Amendment is being submitted in response to the pending Office Action dated October 5, 2005. Amendments to the claims begin on page 2, and Remarks begin on page 6.

THE CLAIMS:

3. (Previously Added) A surgical instrument assembly for treating female urinary stress incontinence comprising:

a mesh for implanting into the lower abdomen of a female to provide support to the urethra;

a curved needle element having a distal end and a proximal end and defining in part a curved shaft, the proximal end being coupled to a first end of the mesh;

a curved needle guide having a proximal end and a distal end; and

a coupling element for coupling the distal end of the needle element to the distal end of the needle guide.

4. (Previously Added) The surgical instrument assembly according to claim 3,

wherein the coupling element has a first bore therein in a first end and a second bore therein in a second end, wherein the first bore is dimensioned to receive the distal end of the needle element and the second bore is dimensioned to receive the distal end of the needle guide.

5. (Previously Added) The surgical instrument assembly according to claim 4, wherein the coupling element is substantially elliptical in shape.

6. (Previously Added) The surgical instrument assembly according to claim 4, wherein the coupling element is a tube element having a varying inner diameter.

7. (Previously Added) The surgical instrument assembly according to claim 4, wherein the coupling element is a tube element having varying inner and outer diameters.

8. (Previously Added) The surgical instrument assembly according to claim 4, wherein the first and second ends of the coupling element are tapered.

9. (Previously Added) A surgical instrument assembly for treating female urinary stress incontinence comprising:

a mesh for implanting into the lower abdomen of a female to provide support to the urethra;

a curved needle element having a distal end and a proximal end and defining in part a curved shaft, the proximal end being coupled to a first end of the mesh; and

a curved needle guide having a proximal end and a distal end;

wherein the distal end of the needle has a bore therein dimensioned to receive the distal end of the needle guide.

10. (Previously Added) A surgical instrument assembly for treating female urinary stress incontinence comprising:

a mesh for implanting into the lower abdomen of a female to provide support to the urethra;

a curved needle element having a distal end and a proximal end and defining in part a curved shaft, the proximal end being coupled to a first end of the mesh; and

a curved needle guide having a proximal end and a distal end, wherein the distal end has a bore therein dimensioned to receive the distal end of the needle element.

11. (Previously Added) The surgical instrument assembly according to claim 10, wherein the distal end of the needle element further comprises a protruding element projecting outwardly therefrom, and the needle guide bore is dimensioned to receive therein the protruding element.

12-15. (Canceled)

16. (Currently Amended) A ~~The~~ surgical instrument assembly for treating female urinary stress incontinence comprising: ~~according to claim 12,~~

a curved needle element having a distal end and a proximal end and defining in part a curved shaft;

a mesh for implanting into the lower abdomen of a female to provide support to the urethra; and

a connecting element coupled to a first end of the mesh and capable of being detachably coupled to the distal end of the needle element,

wherein the connecting element has a first end and a second end, the first end being coupled to the mesh, and the second end further comprises an arm element projecting outwardly therefrom, and wherein the distal end of the needle element has a bore therein dimensioned to receive the arm element to thereby removably couple the mesh to the needle element.

17. (Currently Amended) The surgical instrument assembly according to claim 16 ~~12~~, wherein the distal end of the needle element further comprises a circumferential groove therein, and wherein the connecting element further comprises a flexible loop element coupled thereto, wherein the flexible loop element is capable of engaging the circumferential groove to thereby removably coupled the mesh to the needle element.

18. (Currently Amended) The surgical instrument assembly according to claim 16 ~~12~~, further comprising a second connecting element coupled to a second end of the mesh and capable of being detachably coupled to the distal end of the needle element.

19. (Currently Amended) A method for treating female urinary stress incontinence comprising:

passing a needle guide through a first path through the abdominal wall, along one side of the urethra, and through an anterior wall of the vagina;

attaching a first end of a coupling element to a distal end of the needle guide and a second end of the coupling element to a distal end of a first needle element, the first needle element being coupled to a first end of a mesh;

retracting the needle guide, the first needle element, and mesh back through the abdominal wall substantially via the first path;

uncoupling the needle guide from the coupling element;

passing the needle guide through a second path through the abdominal wall, along an opposite side of the urethra, and through the anterior wall of the vagina;

attaching a first end of a coupling element to a distal end of the needle guide ~~element~~, and a second end of the coupling element to a distal end of a second needle element, the second needle element being coupled to a second end of the mesh; and

retracting the needle guide, second needle element, and mesh back through the abdominal wall substantially via the second path to thereby position the mesh between the urethra and vaginal wall to thereby provide support to the urethra.

20. (Previously Added) The method according to claim 19, wherein the coupling element of the first and second attaching step is the same coupling element.

21. (Canceled) A method for treating female urinary stress incontinence comprising:

passing a needle element defining in part a curved shaft through a first path through the abdominal wall, along one side of the urethra and through an anterior wall of the vagina;

coupling a distal end of the needle element to a first coupling element coupled to a first end of a mesh;

retracting the needle element and mesh back through the abdominal wall substantially via the first path;

uncoupling the needle element from the mesh;

passing the curved needle element through a second path through the abdominal wall, along an opposite side of the urethra and through the anterior wall of the vagina;

coupling a distal end of the needle element to a second coupling element coupled to a second end of the mesh;

retracting the needle element and mesh back through the abdominal wall substantially via the second path to thereby position the mesh to provide support to the urethra; and

uncoupling the needle element from the mesh.

Remarks

Claims 3-25 are currently pending in this application. By this Amendment, claims 4, 16 and 19 have been amended as described further below. Claims 12-15 have been canceled.

Applicant first wishes to thank the Examiner for the indication of allowability with respect to claim 9-11.

With respect to remaining claims, in the outstanding Office Action dated October 5, 2005, claim 12 has been rejected and provisionally rejected on the grounds of obviousness-type double patenting. By this Amendment, claim 12 has been canceled, rendering such rejections moot.

Claim 3 has also been provisionally rejected on the grounds of double patenting over claim 1 of co-pending U.S. Application Ser. No. 09/873,571. By Amendment dated December 13, 2005 (a copy of which is attached hereto), claim 1 has been canceled from U.S. Application Ser. No. 09/873,571, rendering the provisional rejection moot. In view of the foregoing and the fact that no further rejections/objections remain pending with regard to claim 3, applicant believes that this claim is in condition for allowance. Each of claims 4-10, which depend therefrom, are also believed to be in condition for allowance.

Independent claim 19 has been objected for informalities. Applicant has amended claim 19 to recite "attaching a first end of a coupling element to a distal end of the needle guide" rather than a needle element, which applicant believes fully overcomes the Examiner's objection.

Each of claims 12-15 have been canceled, rendering moot any pending related rejections.

Claims 16-17 have been indicated as being allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims. Applicant has rewritten these claims accordingly, and believes that they currently are in condition for allowance.

Claim 18 has also been amended to now depend from amended independent claim 16 rather than original claim 12. As claim 16, as amended, has been indicated by

the Examiner as containing allowable subject matter, applicant believes that claim 18 is also now in condition for allowance.

The outstanding Office Action further states that claims 19-20 "are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent from . . . " Applicant notes, however, that claim 19 is an independent claim, and has only been objected to on formal grounds (see discussion above). In view of applicant's correction of the formal defect, applicant believes that all pending rejections/objections with regard to claim 19 have been overcome. Thus, applicant believes that claim 19, as currently amended, and dependent claim 20 are each in condition for allowance.

Finally, independent claim 21 currently stands rejected under 35 U.S.C. § 102 for various grounds. In the interest of expediting the issuance of this application, applicant has canceled claim 21, rendering such rejections moot.

In view of the foregoing, applicant believes that each of pending claims 3-11 and 16-20, as amended, are in condition for allowance, which is respectfully requested.

Although no fee is believed to be due in connection with this Amendment, the Commissioner is hereby authorized to charge any such fee to deposit Account No. 10-0750/GYN-0124/MJS. This Authorization is being submitted in triplicate.

Respectfully submitted,

/Melissa J. Szanto/

Melissa J. Szanto
Attorney for the Applicants
Reg. No. 40,834

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-1365
DATED: December 13, 2005